

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner  
US Department of Commerce  
United States Patent and Trademark  
Office, PCT  
2011 South Clark Place Room  
CP2/5C24  
Arlington, VA 22202  
ETATS-UNIS D'AMERIQUE  
in its capacity as elected Office

Date of mailing (day/month/year)  
08 January 2001 (08.01.01)

International application No.  
PCT/GB00/01589

Applicant's or agent's file reference

International filing date (day/month/year)  
25 April 2000 (25.04.00)

Priority date (day/month/year)  
23 April 1999 (23.04.99)

Applicant

WILKINSON, John, Alfred

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
23 November 2000 (23.11.00)

☐ in a notice effecting later election filed with the International Bureau on:  
\_\_\_\_\_

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
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1211 Geneva 20, Switzerland

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Authorized officer

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REC'D 03 AUG 2001

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference SC7/52745/001	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/01589	International filing date (day/month/year) 25/04/2000	Priority date (day/month/year) 23/04/1999
International Patent Classification (IPC) or national classification and IPC A01N65/00		
Applicant WILKINSON;JOHN ALFRED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 12 sheets, including this cover sheet.  
  
☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 9 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  23/11/2000	Date of completion of this report  01.08.2001
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Klaver, J  Telephone No. +49 89 2399 8601 

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/01589

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, pages:**

1-29 as originally filed

**Claims, No.:**

1-60 with telefax of 16/07/2001

**Drawings, sheets:**

1/10-10/10 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. The amendments have resulted in the cancellation of:
- ☐ the description, pages:
- ☐ the claims, Nos.:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/01589

☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

**see separate sheet**

6. Additional observations, if necessary:

### III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 20-32, 35 - 37.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 20-32,35-37.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

### IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.



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EXAMINATION REPORT**

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- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
- ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☐ all parts.
- ☒ the parts relating to claims Nos. 1 - 19, 33 (partly), 34 (partly), 38 - 60.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes:	Claims	6,7,9-19,38-40,44-53,56,58,60
	No:	Claims	1-5,8,33,34,41-43,54,55,57,59
Inventive step (IS)	Yes:	Claims	1-19, 33-57,60 (all insofar as novel)
	No:	Claims	58
Industrial applicability (IA)	Yes:	Claims	1-18, 33-47,49-60
	No:	Claims	

2. Citations and explanations  
**see separate sheet**

**VI. Certain documents cited**

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

**see separate sheet**

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**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
**see separate sheet**

### **Item I. 5. Amendments**

Amended claims 38 and 41 are directed at a composition comprising a particular essential oil in a gel carrier galanthamine for use as a medicament for topical administration. Original claim 38 was not restricted to a therapeutical use, but insofar as such a use has been disclosed in the application as filed, it concerns the treatment of parasitic insect infestations on humans or animals. Original claim 40 was directed at a (galanthamine) composition for use in the treatment of a human or animal having a parasitic insect infestation.

There is thus no basis in the application documents as originally filed for further medical or therapeutic effects of topically applied gel based essential oil formulations or galanthamine compositions. The amendments of claims 38 and 41 hence go beyond the disclosure of the application as filed, contrary to Rule 70.2 (c) PCT.

### **Item IV. Lack of unity**

The International Examining Authority agrees with the Searching Authority on its finding that the application does not comply with the requirement of unity of invention.

The International Search Report (ISR) has been established for the following (groups of) inventions, which are not linked together by a novel common inventive concept:

#### **i. Claims 1 - 19, 33 (partly), 34 (partly)**

- A pharmaceutical composition for use in the treatment of a human or animal having a parasitic insect infestation comprising an essential oil obtained from a plant selected from the genera Artemisia, Citrus, Juniperus, Laurus, Myristica, Origanum, Piper or Aloysia in a gel carrier.
- Use of a gel and essential oil as defined above in the manufacture of a pharmaceutical composition for the treatment of a human or animal having a parasitic insect infestation.
- A method of treating a human or animal suffering from a parasitic insect infestation by applying a composition as defined here above.

#### **ii. Claims 38, 39, 40, 53 (partly)**

- Composition comprising an essential oil obtained from a plant selected from the genera Pelargonium, Cymbopogon, Pimpinella, Myrtus (Cretian, Moroccan, organe), Lavandula, Pinus, Melaleuca, Cinnamomum, Apium, Thymus, Hyssopus, Rosemarinus, Cananga, Mentha, Eucalyptus or Vitex in a gel carrier for use as a medicament for topical administration.
- Use of a gel and an essential oil as defined above in the manufacture of a composition

as defined above for the treatment of a human or animal having a parasitic insect infestation.

- Method for killing particular parasitic insects by applying this composition.

**iii. Claims 41 - 52, 53 (partly)**

- Composition comprising the alkaloid galanthamine for use as a medicament for topical administration.

- Use of galanthamine or an extract of Narcissus in the manufacture of a composition for treating a human or animal suffering from a parasitic insect infestation.

- Method of treating a human or animal suffering from a parasitic insect infestation by applying the composition defined here above.

- Method suitable for treating furnishing, clothing or plants to kill parasitic insects by applying the composition defined here above.

Method of killing particular parasitic insects by application of the compositions defined above.

**iv. Claims 54 - 60**

- Use of a gel carrier and one or more of various specified terpenes and terpenoids shown to have insecticidal activity for the preparation of a medicament for treating humans or animals having a parasitic insect infestation suitable for topical administration.

- Use of one or more of the specified terpenes or terpenoids at a concentration of 4% by wt. or above for the preparation of a medicament for treating humans or animals having a parasitic insect infestation.

Method suitable for treating clothing, furnishing or plants to kill parasitic insects by exposing the substrates to a gel carrier and one or more of the terpenes or terpenoids defined above.

The inventions numbered i. - iv. are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The common feature linking together the inventions numbered i., ii. and iv. is the parasiticidal (in particular pediculicidal) effect of essential oils or certain ingredients thereof. This effect is known from the prior art (see, inter alia, CH 688 787 A5, WO 96/14046 A1, JP 10 120 519 A and WO96/37210 A1 (example 4) for essential oils as mentioned in claims 1 or 38 and US 4,933,371 for a terpenoid of claim 54).

Compositions comprising an essential oil derived from genera as defined in claim 1 for use in a first medical treatment furthermore also are known in the art as can be seen from, inter alia, WO 96/37210 A2. The 'medical-use' feature in independent claims 1, 20, 22, 33 and 54 hence cannot be used as a unifying feature for the claimed compositions.

Moreover, invention Nr. ii. defines essential oils obtained from other plant genera than the ones defined in claims 1, 20 or 22. For this reason alone, this invention is not linked by a common general inventive concept to the invention Nr. i. either.

The alkaloid galanthamine is not considered an essential oil and the compositions/use or methods as defined by claims 40 - 51 and 52 (partly) (invention Nr. iii.) hence are not linked by a common general inventive concept to the compositions or methods of the other claims.

The compositions used in invention Nr. iv. may contain a range of terpenes or terpenoids, all of which are known to possess insecticidal or miticidal activity. See for example US 4,933,371 and the last 5 documents cited in the ISR.

The gel-formulation is not a unifying novel feature, since invention Nr. iii. is not restricted to gel formulations and, moreover, gels comprising essential oils are known from the prior art (WO 95/23815 A1, CH 688 787 A5, EP 495 684 A1 and WO 94/09631). The medical (topical) use indication of (some of) the claimed gels is not considered sufficient as a unifying inventive concept for inventions Nrs. i., ii. and iv. since method-claims 53, 59 and 60 are directed at non-medical uses and therapeutic gels comprising active ingredients as defined by claim 54 are known from (e.g.) WO 94/09631 A1.

#### **Item V. Novelty, inventive step and industrial applicability.**

For the assessment of the present claims 19 and 48 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

#### **Invention Nr. i (claims 1 - 19, 33 (partly), 34 (partly))**

a). Claims 1 - 5 and 8 are not novel within the meaning of Art. 33 (2) PCT for the following reason:

WO 95/23815 A1 (= D12) discloses in example 9 a (pharmaceutical) composition comprising about 3% of an essential oil obtained from *Juniperus* in an agar based gel carrier which is effective in the treatment of acne. Since acne normally is considered a skin disease, said composition anticipates the pharmaceutical compositions of claims 1 - 5, 8 33 and 34, at least insofar as the active ingredient derives from *Juniperus*.

b). Pharmaceutical compositions as defined by present claim 1 for use in the treatment of humans or animals having a lice infestation comprising gels with essential oils obtained from plants other than *Juniperus* have not been disclosed in the available prior art.

JP 63 260 956 A (= D10) discloses fragrant gels and WO 97/17944 A1 (= D11) discloses agar based gels for cosmetic applications.

CH 688 787 A5 (= D1) and EP 495 684 A1 (= D4) disclose, that essential oil comprising gels may be used as an alternative for antiparasitic shampoos. D4 moreover only discloses a lice-repellent effect, which is less for gels than for a spray (D4: page 9, line 15 - 18).

Example 1a of the application discloses, that gel-based formulations of sage oil have a much lower LD<sub>50</sub> value than isopropylalcohol/water based formulations.

It follows from Figures 3 and 4, that it is plausible to expect an analogous enhanced pediculicidal effect of gels comprising other essential oils.

Such an advantageous effect of gel based formulations of essential oils of claim 1 is not derivable from the available prior art

The subject-matter of claims 1 - 19, 33 and 34 (the latter insofar as dependent on claims 1 - 17), insofar as clearly and unequivocally distinguished from D12, hence is novel and based on an inventive step (Art. 33 (2) and (3) PCT).

#### **Invention Nr. ii (claims 38 -40, 53 (partly))**

a). Insofar as the compositions of claim 38 and 39 are directed at the topical application as a medicament for treatment of humans or animals having a parasitic infestation, they are novel with respect to the prior art since none of the citations of the International Search Report disclose gels comprising essential oils as defined by claim 38 for such a therapeutic use. The only document disclosing such gels for therapeutically controlling parasite infestation is WO 97/47193 A1 (= D13). The gels used in this document, however, are slow release formulations for use in a bee hive and are not intended for topical use on humans or animals.

D1 discloses the antiparasitic effect of (topically applied) essential oils and mentions gels

as a possible formulation without giving a specific example of such a formulation.

WO 96/37210 A2 (= D9) discloses pharmaceutical compositions comprising essential oils for topical use, but does not disclose gels.

The subject-matter of claims 38 - 40 hence is novel with respect to the prior art (Art. 33 (2) PCT).

The subject-matter of claim 53 ((non-therapeutic) method of killing specified parasitic insects by using the gels of claims 38 and 39) also is novel over the prior art. See, however, item VIII below.

b). The inventive step underlying the claims can be accepted for essentially the same reasons as given above for invention Nr. i.

Claims 38 - 40 and 53 hence also meet the criterion set forth in Art. 33 (3) PCT.

**Invention Nr. iii (claims 41 - 52, 53 (partly))**

a). Compositions comprising galanthamine for use as a medicament for topical administration as defined by claims 41 - 43 are anticipated by the therapeutic galanthamine formulations of US 5,519,017 (= D17) and WO 96/29332 A1 (= D18). Said documents disclose therapeutic galanthamine compositions for transdermal delivery or for use as an eye ointment which both are within the scope of the term 'for topical administration'.

Claims 41 - 43 hence are not novel (Art. 33 (2) PCT).

Incorporation of the feature 'for treatment of a human or animal suffering from a parasitic insect infestation' into these claims would render the claimed compositions novel with respect to D17 and D18 since such a treatment does not require transdermal delivery of the active ingredient.

b). Gels comprising galanthamine or compositions comprising 0.1 - 20% alcohol have not been disclosed in the available prior art. The subject-matter of claim 44 - 46 hence is novel.

The subject-matter of claims 47 - 53 (the latter insofar as dependent on claims 41 - 46) also is novel over the prior art, since none of the documents D17, D18 or Numata et al. (= D16) disclose a parasitocidal (pediculicidal) effect of galanthamine.

c). D16 discloses the potent antifeeding and insecticidal activity of galanthamine against

larvae of the yellow butterfly. A parasiticial (pediculicidal) effect of galanthamine as demonstrated in example 5 of the application has not been disclosed or suggested in this document or in any other citation of the ISR.

The subject-matter of claims 44 - 53 (insofar as dependent on claims 41 - 46) hence is considered to be based on an inventive step (Art. 33 (3) PCT).

**Invention Nr. iv (claims 54 - 60)**

a). US 4,379,168 (= D22) discloses gels comprising limonene used for the topical treatment of animals suffering from insect (lice) infestation: see D22, col. 6, line 66 - col. 7, line 4.

D22 hence anticipates the novelty of claims 54, 55 and 57.

The addition of further terpenes or terpenoids to such compositions in order to enhance their efficacy is obvious in view of US 4,933,371 (D5). Claims 58 hence is not inventive.

JP 4 139 104 A (= D20) discloses gels comprising terpenes such as sabinene, limonene, camphor etc. for use against household mites and anticipates the novelty of the method as defined by claim 59.

b). Since none of the citations of the ISR disclose the use of gels comprising terpenes or terpenoids other than limonene for the topical treatment of humans or animals suffering from parasitic insect infestation, claims 54 - 58 are novel for these embodiments.

Method for treating plants using such gels have not been disclosed in the available prior art. Claim 60 hence is novel.

c). Claims 54 - 58 and 60, insofar as novel, are considered inventive (Art. 33 (3) PCT), since it can be seen from Fig. 7 - 9 and Example 2a, that gel based formulations have a much stronger parasiticial effect than the oil based formulations of the same active ingredients. Such an effect is not derivable from the available prior art.

**Item VI Certain documents cited**

The following documents were published after the priority date of 23.04.99 GB as claimed by the present application: WO 00/00213 A1 (= D2) (publication date: 06.01.00), WO 99/37148 A1 (= D6) (PD: 29.07.99) and GB 2 341 091 A (= D7) (PD: 08.03.00).

The priority document is silent on gel based formulations or the use thereof. The priority hence only has been validly claimed for the subject-matter of claims 20 - 32, 33 and 34

(both insofar as dependent on claims 20 - 32), 35 - 37, 41 - 43 and 47 - 53 insofar as these claims do not relate to gel based formulations or the use thereof.

D2, D6 and D7 thus do not form part of the prior art of these parts of the application (Rule 64.1 (b) (ii) PCT) but are comprised in the prior art of all other claims, including all gel-based embodiments.

D2 discloses compositions for the treatment of head lice comprising 0,5 - 50% of an essential oil in a carrier fluid such as an alcohol or a non-essential oil. D2 does not disclose compositions based on gel carriers.

D6 discloses pharmaceutical formulations for the treatment of lice or lice eggs comprising one or more terpenes in an aqueous carrier. D6 does not disclose gel based carriers.

D7 discloses a method for the treatment of head lice using shampoo formulations comprising particular essential oil combinations. D7 does not disclose gel based formulations.

#### **Item VII. Certain defects**

- Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1, D3, D5, D9 and D17 is not mentioned in the description, nor are these documents identified therein.
- The reference in Example 5 ('M. Ryan') is incomplete.

#### **Item VIII. Clarity**

The following objections are raised pursuant to Art. 6 PCT:

- The term 'carbomer' in claim 7 is ambiguous. it is not clear to which compound or class of compounds this term refers. In case the same gelling agent as is used in the compositions of D4 is intended, this term cannot be used in the claim since it refers to a trade mark which may only be used if they are generally recognized as having a precise meaning (Guidelines PCT Ch. III §4.5b (March 1993)).
- Various embodiments of the claims are not present in the description (claims 7 and claims 13 - 17), resulting in doubts regarding the intended scope of protection.
- The intended scope of claims 38, 39 and 41 - 46 is obscured by the fact, that (non-therapeutic, non-medical) method claim 53 uses the same (medical/therapeutic) formulations as defined by said claims 38, 39 and 41 - 46.

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**CLAIMS:**

1. A pharmaceutical composition comprising an essential oil in a gel carrier, said essential oil  
5 being obtained from a plant selected from the genera *Salvia*, *Artemisia*, *Citrus*, *Juniperus*, *Laurus*, *Myristica*, *Origanum*, *Piper* or *Aloysia*, said composition being for use in the treatment of a human or animal having a parasitic insect infestation.
- 10 2. A composition as claimed in claim 1 wherein the concentration of essential oil is from about 0.1 to about 50% w/v of the composition.
- 15 3. A composition as claimed in claim 2 wherein the concentration of essential oil is from about 0.1 to about 8% w/v of the composition.
- 20 4. A composition as claimed in claim 3 wherein the concentration of essential oil is about 4% w/v of the composition.
- 25 5. A composition as claimed in any preceding claim wherein the gel is based on agar, agarose, gelatin or a synthetic gelling agent.
- 30 6. A composition as claimed in claim 5 wherein the synthetic gelling agent is a gel based on glyceryl polymethacrylate and propylene glycol.
- 35 7. A composition as claimed in claim 4 or claim 5 wherein the gel is a carbomer.
8. A composition as claimed in any one of claims 5 to 7 wherein the gelling agent contains about 0.1 to about 95%, preferably about 0.1 to about 66% water v/v and/or alcohol, preferably isopropyl alcohol (IPA) at

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about 0.1% to about 20% v/v.

9. A composition as claimed in any preceding claim wherein said essential oil is obtained from  
5 *Salvia lavandulifolia* or *Salvia officinalis*.

10. A composition as claimed in any one of claims 1 to 8 wherein said essential oil is obtained from a plant of the genera *Citrus*.  
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11. A composition as claimed in any one of claims 1 to 8 which includes essential oil obtained from the plant genera *Salvia* and *Citrus*.

12. A composition as claimed in claim 9 which comprises the essential oil of *Salvia lavandulifolia* at about 4% w/v dispersed in a gel diluted about 1:2 v/v with water.  
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13. A composition as claimed in any preceding claim comprising an anti-pruritic agent.  
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14. A composition as claimed in claim 13 wherein said anti-pruritic agent is *Aloe vera*.  
25

15. A composition as claimed in claim 14 wherein said composition includes *Aloe vera* gel.

16. A composition as claimed in claim 15 which comprises about 0.1 to about 5.0% w/v *Aloe vera* gel.  
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17. A composition as claimed in any one of claims 12 to 16 which comprises about 0.5% w/v *Aloe vera* gel.  
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18. Use of a gel and essential oil selected from the essential oils defined in claim 1 in the

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manufacture of a composition as claimed in any one of claims 1 to 17 for the treatment of a human or animal having a parasitic insect infestation.

5           19. A method of treating a human or animal  
suffering from a parasitic insect infestation  
comprising applying to said human or animal a  
composition as claimed in any one of claims 1 to 17.

10           20. A composition comprising an essential oil in  
an aqueous alcoholic vehicle wherein said vehicle  
comprises from about 0.1% up to about 20% alcohol v/v  
with water and wherein said essential oil is obtained  
15 from a plant selected from the genera *Salvia*,  
*Artemisia*, *Citrus*, *Juniperus*, *Laurus*, *Myristica*,  
*Origanum*, *Piper* or *Aloysia*, said composition being for  
use in the treatment of a human or animal having a  
parasitic insect infestation.

20            21. A composition as claimed in claim 20 wherein  
said vehicle comprises about 20% v/v alcohol with  
water.

22. A composition comprising an essential oil in  
a vehicle comprising an alcohol/vegetable oil mixture  
wherein said alcohol is present in said vehicle in an  
amount of about 0.1% up to about 20% v/v and wherein  
said essential oil is obtained from a plant selected  
from the genera *Salvia*, *Artemisia*, *Citrus*, *Juniperus*,  
*Laurus*, *Myristica*, *Origanum*, *Piper* or *Aloysia* said  
composition being for use in the treatment of an  
animal having a parasitic insect infestation.

23. A composition as claimed in claim 22 wherein  
35 said vehicle comprises about 20% alcohol v/v.

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24. A composition as claimed in any one of claims 20 to 23 wherein the alcohol is isopropyl alcohol.

5 25. A composition as claimed in any one of claims 20 to 24 wherein said essential oil is obtained from *Salvia lavandulifolia* or *Salvia officinalis*.

10 26. A composition as claimed in any one of claims 20 to 24 wherein said essential oil is obtained from a plant of the genera *Citrus*.

15 27. A composition as claimed in any one of claims 20 to 24 wherein said essential oil is obtained from the genera *Salvia* and *Citrus*.

20 28. A composition as claimed in any one of claims 20 to 27 which is formulated as a dip, spray or pour-on treatment.

25 29. Use of an aqueous alcoholic vehicle and an essential oil as defined in claim 20 in the manufacture of a composition for the treatment of a human or animal having a parasitic insect infestation.

30 30. A method of treating a human or animal suffering from a parasitic insect infestation comprising applying to said human or animal a composition as claimed in any one of claims 20, 21, 24, 25, 26, 27 and 28.

35 31. Use of a vegetable oil/alcohol vehicle and an essential oil as claimed in claim 22 in the manufacture of a medicament for the treatment of an animal having a parasitic insect infestation.

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32. A method of treating an animal having a parasitic insect infestation comprising applying to said animal a composition as claimed in any of claims 22 to 28.

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33. A composition for use as claimed in any one of claims 1 to 17 and 20 to 28 wherein said parasitic insects are selected from lice, lice eggs, mites, fleas or parasites associated with blowfly strike.

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34. A composition as claimed in claim 33 wherein said parasitic insects are selected from head lice (*Pediculus humanus capitis*, syn. *P. capitis*), clothing lice (*Pediculus humanus humanus* syn. *P. corporis*), pubic lice (*Phthirus pubis*), biting lice (*Bovicula ovis*), scab mite (*Psoroptes ovis*), ear mite (*Psoroptes cuniculi*), dust mites (primarily of the genus *Dermatophagoides*, pig mites, cat fleas (*Ctenocephalides felis*), dog fleas (*C. canis*), horse fleas and *Lucilia* or *Chrysomya* species.

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35. A method suitable for treating furnishing or clothing to kill parasitic insects which comprises exposing said furnishings to a composition of the type defined in any one of claims 20, 21, 24, 25, 26, 27 and 29.

25

36. A method suitable for treating plants to kill parasitic insects which comprises applying to said plants a composition of the type defined in any one of claims 20, 21, 24, 25, 26, 27 and 29.

30

37. A method as claimed in claim 36 wherein said parasitic insects are selected from the genera *Aphis*, *Chilo*, *Dysderus*, *Megoura*, *Musca*, *Pieris*, *Nilaparvata*, *Nephotettix*, *Tetranychus*, *Trialeurodes*, *Thysanoptera*

35

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or *Lepidoptera*.

38. A composition comprising an essential oil in a gel carrier, said essential oil being obtained from a plant selected from the genera *Pelargonium*,  
5 *Cymbopogon*, *Pimpinella*, *Myrtus* (cretian, Moroccan, organe), *Lavandula*, *Pinus*, *Melaleuca*, *Cinnamomum*, *Apium*, *Thymus*, *Hyssopus*, *Rosemarinus*, *Cananga*, *Mentha*, *Eucalyptus* or *Vitex* for use as a medicament for  
10 topical administration.

39. A composition as claimed in claim 38 wherein said gel is as defined in any one of claims 5 to 7.

40. Use of a gel and an essential oil defined in claims 38 or 39 in the manufacture of a composition as claimed in claim 38 or 39 for the treatment of a human or animal having a parasitic insect infestation.

41. A composition comprising the alkaloid galanthamine for use as a medicament for topical administration.

42. A composition for use as claimed in claim 41 wherein said composition comprises an extract of a plant of the genus *Narcissus*.

43. A composition for use as claimed in claim 41 or 42 wherein said galanthamine or extract is  
30 dissolved in an oil-based medium, a water/alcohol based medium or is formulated as a hair conditioner or shampoo or as a gel, dip or pour on treatment.

44. A composition as claimed in claim 43 wherein  
35 said gel is as defined in any one of claims 5 to 7.

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45. A composition as claimed in claim 43 wherein said galanthamine or extract is carried in a vehicle comprising from about 0.1 to about 20% alcohol (v/v).

5           46. A composition as claimed in claim 45 wherein said vehicle comprises about 20% v/v isopropyl alcohol.

10           47. Use of galanthamine or an extract of *Narcissus* in the manufacture of a composition for treating a human or animal suffering from a parasitic insect infestation.

15           48. A method of treating a human or animal suffering from a parasitic insect infestation which comprises applying to said human or animal a composition as claimed in any one of claims 41 to 46.

20           49. A composition for use as claimed in any one of claims 41 to 46 wherein said parasitic insects are selected from lice, lice eggs, mites, fleas or parasites associated with blowfly strike.

25           50. A composition for use as claimed in claim 49 wherein said parasitic insects are selected from head lice (*Pediculus humanus capitis*, syn. *P. capitis*), clothing lice (*Pediculus humanus humanus* syn. *P. corporis*), pubic lice (*Phthirus pubis*), biting lice (*Bovicula ovis*), scab mite (*Psoroptes ovis*), ear mite (*Psoroptes cuniculi*), dust mites (primarily of the genus *Dermatophagoides*), pig mites, cat fleas (*Ctenocephalides felis*), dog fleas (*C. canis*), horse fleas and *Lucilia* or *Chrysomya* species.

35           51. A method suitable for treating furnishing or clothing to kill parasitic insects which comprises



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57. Use of one of the terpenes and terpenoids selected from the group consisting of: sabinene, sabinene(+), sabinene(-), limonene(D), limonene(L), caryophyllene, myrcene, tepinen-4-ol, p-cymene, borneol, camphor, p-cymene, a-terpineol, camphene, a-pinene, b-pinene, linalool, 1,8-cineol, a/b thujone, camphene, at a concentration of about 4% by weight or above for the preparation of a medicament for treating humans, animals having a parasitic insect infestation.

58. The use of claim 57 modified to include one or more further terpene or terpenoid compounds from said group.

59. A method suitable for treating furnishing or clothing to kill parasitic insects which comprises exposing said furnishing and clothing to a gel carrier and one or more of the terpenes and terpenoids, as defined in any one of claims 54-58.

60. A method suitable for treating plants to kill parasitic insects which comprises applying to said plants a gel carrier and one or more of the terpenes, terpenoids as defined in any one of claims 54-58.

: 309380; SLM; LP: LONDOCS

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/GB 00/ 01589</b>	International filing date (day/month/year) <b>25/04/2000</b>	(Earliest) Priority Date (day/month/year) <b>23/04/1999</b>
Applicant <b>WILKINSON; JOHN ALFRED</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 9 sheets.  
☒ It is also accompanied by a copy of each prior art document cited in this report.

### 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☒ Unity of invention is lacking (see Box II).

### 4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

### 5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

### 6. The figure of the drawings to be published with the abstract is Figure No.

- ☐ as suggested by the applicant.
- ☐ because the applicant failed to suggest a figure.
- ☐ because this figure better characterizes the invention.
- ☒ None of the figures.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/GB 00/01589

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:  
  
1-19, 33, 34, 38-57
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-19, 33 (partly), 34 (partly)

A composition for use in the treatment of a human or animal having a parasitic insect infestation comprising an essential oil obtained from a plant selected from the genera Artemisia, Citrus, Juniperus, Laurus, Myristica, Origanum, Piper or Aloysia in a gel carrier.

Use of a gel and essential oil as defined above in the manufacture of a composition for the treatment of a human or animal having a parasitic insect infestation.

A method of treating a human or animal suffering from a parasitic insect infestation by applying a composition as defined hereabove.

2. Claims: 20, 21, 29, 30 (partly), 33 - 37 (all partly),  
52 (partly)

A composition for use in the treatment of a human or animal having a parasitic insect infestation comprising an essential oil obtained from a plant selected from the genera Artemisia, Citrus, Juniperus, Laurus, Myristica, Origanum, Piper or Aloysia in an aqueous alcoholic vehicle comprising from 0.1% - 20% v/v alcohol with water.

Use of a composition as defined above in the manufacture of a composition for the treatment of a human or animal having a parasitic insect infestation.

Method of treating a human or animal suffering from a parasitic insect infestation by applying the composition defined hereabove.

Method suitable for treating furnishing, clothing or plants to kill parasitic insects by applying the composition defined hereabove.

3. Claims: 22-28, 30 (partly), 31, 32, 33 - 37 (all partly),  
52 (partly)

A composition for use in the treatment of a human or animal having a parasitic insect infestation comprising an essential oil obtained from a plant selected from the genera Artemisia, Citrus, Juniperus, Laurus, Myristica, Origanum, Piper or Aloysia in an alcohol/vegetable oil mixture comprising from 0.1% - 20% v/v alcohol.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Use of a composition as defined above in the manufacture of a composition for the treatment of a human or animal having a parasitic insect infestation.

Method of treating a human or animal suffering from a parasitic insect infestation by applying the composition defined hereabove.

Method suitable for treating furnishing, clothing or plants to kill parasitic insects by applying the composition defined hereabove.

4. Claims: 38, 39, 52 (partly)

Composition comprising an essential oil obtained from a plant selected from the genera Petergonium, Cymbopogon, Pimpinella, Myrtus (Cretian, Moroccan, organe), Lavandula, Pinus, Melaleuca, Cinnamomum, Apium, Thymus, Hyssopus, Rosmellus, Cananga, Mentle, Eucalyptus or Vitex in a gel carrier.

Method for treating plants to kill insects by applying this composition.

5. Claims: 40- 51, 52 (partly)

Composition comprising the alkaloid galanthamine for use in the treatment of a human or animal having a parasitic insect infestation.

Use of galanthamine or an extract of Narcissus in the manufacture of a composition for treating a human or animal suffering from a parasitic insect infestation.

Method of treating a human or animal suffering from a parasitic insect infestation by applying the composition defined hereabove.

Method suitable for treating furnishing, clothing or plants to kill parasitic insects by applying the composition defined hereabove.

6. Claims: 53 - 57

Composition comprising a gel carrier and one or more of the terpenes and terpenoids shown to have insecticidal activity for use in treating humans, animals, clothing, furnishing and plants (preferably selected from sabinene, p-cymene, beta-pinene, myrcene, limonene and terpinen-4-ol).

## INTERNATIONAL SEARCH REPORT

International Application No

P GB 00/01589

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A01N65/00 A01N25/04 A01N25/02 A61K35/78 A61K7/40

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A01N A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, EP0-Internal, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CH 688 787 A (LINSIG DIETER ; RICHLI THOMAS (CH)) 31 March 1998 (1998-03-31) column 2, line 4,15-42,60 column 3, line 6-14,18,19,34-37; example 2 ---	1-39, 52-57
P,X	WO 00 00213 A (ARBOR VIDA NATURAL PRODUCTS ; WOLFF RICKI DE (US)) 6 January 2000 (2000-01-06) cited in the application page 2, line 14-24 page 3, line 3 -page 4, line 28 page 5, line 1 -page 6, line 2; table 1 --- -/--	20-39, 52-57

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&amp;" document member of the same patent family

Date of the actual completion of the international search

29 September 2000

Date of mailing of the international search report

12.5.10.00

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Klaver, J

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/GB 00/01589

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	PATENT ABSTRACTS OF JAPAN vol. 1998, no. 10, 31 August 1998 (1998-08-31) & JP 10 120519 A (OSAKA SEIYAKU:KK), 12 May 1998 (1998-05-12) abstract ----	1-37, 52
X	EP 0 495 684 A (CLILCO LTD) 22 July 1992 (1992-07-22) cited in the application  see: page 2, line 44-50; page 3, line 48-56; page 4, line 11 - 13; page 7, line 47/48. ----	1-5, 7-9, 11, 12, 20-25, 28, 33, 34, 38, 39, 53-57
X	US 4 933 371 A (HINK W FREDRIC ET AL) 12 June 1990 (1990-06-12) column 1, line 31-38 column 3, line 63 - column 4, line 19 column 7, line 32-38 column 20, line 9-23 ----	53-57
P, X	WO 99 37148 A (XIMED GROUP PLC ; FRANKLIN LANNY (US)) 29 July 1999 (1999-07-29) see: page 1, par. 3; page 11, par. 4; page 13, par. 1-3. ----	53-57
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X	WO 96 14046 A (UNIV RAMOT ; ROSENBERG MELVYN (IL)) 17 May 1996 (1996-05-17) page 1, paragraph 2 page 3, paragraph 4; examples 3, 7 ----	1-39, 52-57
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## INTERNATIONAL SEARCH REPORT

International Application No

P 01589

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	<p>WO 97 47193 A (WATKINS MAX; VITA EUROP LTD  (GB)) 18 December 1997 (1997-12-18)  page 2, paragraph 3  page 3, paragraph 5  page 5, paragraph 6; examples 1-4</p> <p>---</p>	38,39, 53-57
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X	<p>WO 98 22152 A (GUINANE PTY LTD P; CRAWFORD  IAN (AU); TEETEEOH RESEARCH GROUP PTY)  28 May 1998 (1998-05-28)  page 3, line 1-17  page 4, line 1-19; examples 1-12</p> <p>---</p>	38,39
X	<p>A. NUMATA ET AL.: "Antifeedants for the  larvae of the Yellow Butterfly, Eurema  hecabe, in Lycoris radiata"  CHEM. PHARM. BULL.,  vol. 31, no. 6, 1983, pages 2146-2149,  XP002148848  page 2149, line 5-19</p> <p>---</p>	40-42, 48-52
X	<p>US 5 519 017 A (OPITZ KLAUS)  21 May 1996 (1996-05-21)   column 4, line 1-41  column 5, line 12-31</p> <p>---</p>	40-42, 44,45, 48,49
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## INTERNATIONAL SEARCH REPORT

International Application No

P GB 00/01589

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 29332 A (LOHMANN THERAPIE SYST LTS; HILLE THOMAS (DE); HOFFMANN HANS RAINER) 26 September 1996 (1996-09-26) page 4, line 1-20 ---	40-42, 44,45, 48,49
X	WO 94 09631 A (GISQUARE TECH BV; ROVESTI GUIDO (IT); SEGALLA GABRIELE (IT); FRATT) 11 May 1994 (1994-05-11) page 6, line 1-20 page 7, line 15-26; examples 5-11 ---	53,54, 56,57
X	DATABASE WPI Section Ch, Week 199226 Derwent Publications Ltd., London, GB; Class A96, AN 1992-211969 XP002148849 & JP 04 139104 A (ARAKAWA CHEM IND LTD), 13 May 1992 (1992-05-13) cited in the application abstract ---	53-57
X	DATABASE WPI Section Ch, Week 198005 Derwent Publications Ltd., London, GB; Class A97, AN 1980-08537C XP002148850 & JP 54 160739 A (DASUKIN FRANCHISE K), 19 December 1979 (1979-12-19) abstract ---	53-57
X	US 4 379 168 A (DOTOLO VINCENT) 5 April 1983 (1983-04-05) column 2, line 11-33 column 6, line 66 -column 7, line 4 ---	53-57
X	S. PERRUCCI & G. MACCHIONI: "Structure/activity relationship of some natural monoterpenes as acaricides against Psoroptes cuniculi." J. NATURAL PRODUCTS, vol. 58, no. 8, August 1995 (1995-08), pages 1261-1264, XP000916948 page 1261, column 1, paragraph 2 -column 2, paragraph 1 page 1262, column 1, paragraph 1 -column 2, paragraph 1; table 1 ---	53-57
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## INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/01589

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>C. REGNAULT-ROGER ET AL.: "Insecticidal effect of essential oils from mediterranean plants upon Acanthoscelides obtectus say (Coleoptera, Bruchidae), a pest of kidney bean." J. CHEM. ECOLOGY, vol. 19, no. 6, 1993, pages 1233-1244, XP000940842 see: 'Discussion' and Table 1. -----</p>	53-57

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/01589

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